IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF VIRGINIA CHARLOTTESVILLE DIVISION

UNIVERSITY OF VIRGINIA PATENT FOUNDATION,

> Plaintiff and Counterclaim-Defendant,

CASE NO.: 3:08-cv-00025-nkm V.

GENERAL ELECTRIC COMPANY d/b/a GE HEALTHCARE and PHILIPS ELECTRONICS NORTH AMERICA CORP. d/b/a PHILIPS HEALTHCARE,

> Defendants and, as to GE, Counterclaimant.

DEFENDANT GENERAL ELECTRIC COMPANY'S ANSWER AND AFFIRMATIVE DEFENSES

Defendant and counterclaimant General Electric Company ("GE"), by and through the undersigned counsel, answers the Complaint of plaintiff and counterclaim-defendant University of Virginia Patent Foundation ("UVAPF") as follows:

ANSWER

I. THE PARTIES

- 1. GE lacks sufficient information to form a belief as to the truth or falsity of the allegations in paragraph 1 of the Complaint and therefore denies them.
- 2. GE admits that it is a New York corporation having a principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut 06828 and that it does business as GE

Healthcare. Except as expressly admitted, GE denies the remaining allegations of paragraph 2 of the Complaint.

3. GE lacks sufficient information to form a belief as to the truth or falsity of the allegations in paragraph 3 of the Complaint and therefore denies them.

II. JURISDICTION AND VENUE

- 4. GE admits that this action purports to arise under the patent laws of the United States, including 35 U.S.C. § 271. GE admits that Plaintiff purports to invoke subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Except as expressly admitted, GE denies the remaining allegations of paragraph 4 of the Complaint.
- 5. GE admits that it has conducted business within the State of Virginia and the Western District of Virginia. Except as expressly admitted, GE denies the remaining allegations of paragraph 5 of the Complaint.
- 6. GE lacks sufficient information to form a belief as to the truth or falsity of the allegations in paragraph 6 of the Complaint and therefore denies them.
- 7. GE lacks sufficient information to form a belief as to the truth or falsity of the allegations in paragraph 7 of the Complaint and therefore denies them.

III. ALLEGED PATENT INFRINGEMENT

- 8. Denied.
- 9. GE lacks sufficient information to form a belief as to the truth or falsity of the allegations in paragraph 9 of the Complaint and therefore denies them.
 - 10. Denied.
 - 11. Denied.

- 12. GE lacks sufficient information to form a belief as to the truth or falsity of the allegations in paragraph 12 of the Complaint and therefore denies them.
 - 13. Denied.
 - 14. Denied.
 - 15. Denied.
 - 16. Denied.

IV. PRAYER FOR RELIEF

GE denies that UVAPF is entitled to the relief it seeks or to any relief at all for the allegations made in the Complaint.

AFFIRMATIVE DEFENSES

For its Affirmative Defenses to the Complaint, GE alleges as follows:

FIRST AFFIRMATIVE DEFENSE (Failure to State a Claim)

1. UVAPF's Complaint fails to state a claim against GE upon which any relief can be granted.

SECOND AFFIRMATIVE DEFENSE (Non-Infringement)

2. GE has not infringed, and currently does not infringe, United States Patent No. 5,245,282 (the "'282 Patent") directly, indirectly, by contribution, by inducement, under the doctrine of equivalents, or in any other manner.

THIRD AFFIRMATIVE DEFENSE (Safe Harbor)

3. GE is not liable for acts that UVAPF alleges infringe the '282 Patent because the accused activities are reasonably related to the development and submission of information under

a Federal law which regulates the manufacture, use or sale of medical devices under 35 U.S.C. § 271(e)(1).

FOURTH AFFIRMATIVE DEFENSE (Invalidity)

4. The claims of the '282 Patent are invalid for failure to satisfy one or more of the conditions for patentability specified in Title 35 of the United States Code, including without limitation Sections 101, 102, 103 and 112.

FIFTH AFFIRMATIVE DEFENSE (Waiver)

5. UVAPF is barred from asserting the claims of the '282 Patent against GE by the doctrine of waiver.

SIXTH AFFIRMATIVE DEFENSE (Estoppel)

6. UVAPF is barred from asserting the claims of the '282 Patent against GE by the doctrine of estoppel.

SEVENTH AFFIRMATIVE DEFENSE (Prosecution History Estoppel)

7. UVAPF is estopped from asserting that the use of GE's products is included within the scope of the claims of the '282 Patent by the doctrine of prosecution history estoppel.

EIGHTH AFFIRMATIVE DEFENSE (License)

8. GE is not liable for acts that UVAPF alleges infringe the '282 Patent because GE has license rights under the '282 Patent, including but not limited to rights UVAPF licensed to GE in connection with a multi-center clinical study known as the Alzheimer's Disease Neuroimaging Initiative, or ADNI, conducted by the National Institute on Aging, an Institute of the National Institutes of Health.

NINTH AFFIRMATIVE DEFENSE (Laches)

UVAPF's claims for relief against GE as set forth in the Complaint are barred by 9. the doctrine of laches.

TENTH AFFIRMATIVE DEFENSE (Bayh-Dole Act Violations)

On information and belief, UVAPF is precluded from enforcing the '282 Patent 10. because, inter alia, it has not complied with the provisions of the Bayh-Dole Act, 35 U.S.C. § 200, et seg.

ELEVENTH AFFIRMATIVE DEFENSE (Unclean Hands)

UVAPF is barred from asserting the claims of the '282 Patent against GE by the 11. doctrine of unclean hands.

JURY DEMAND

GE hereby demands a jury trial on all issues and claims so triable.

PRAYER FOR RELIEF

WHEREFORE, GE prays for judgment with respect to UVAPF's Complaint and GE's Affirmative Defenses as follows:

- that judgment be entered against UVAPF and in favor of GE on each of the a. claims set forth in the Complaint filed by UVAPF and that each such claim be dismissed with prejudice;
- that the Court find this an exceptional case and award GE its costs and attorneys' b. fees pursuant to 35 U.S.C. § 285 or otherwise; and

c. that the Court grant GE such other and further relief as the Court deems just and proper.

DATED: September 19, 2008

McGUIRE WOODS LLP

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Attorneys for Defendant GENERAL ELECTRIC COMPANY d/b/a GENERAL ELECTRIC HEALTHCARE

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GENERAL ELECTRIC COMPANY d/b/a GE HEALTHCARE and PHILIPS ELECTRONICS NORTH AMERICA CORP. d/b/a PHILIPS HEALTHCARE,

> Defendants and, as to GE, Counterclaimant.

GENERAL ELECTRIC COMPANY'S COUNTERCLAIMS OF NON-INFRINGEMENT **AND INVALIDITY OF THE '282 PATENT**

Defendant and counterclaimant General Electric Company ("GE"), by and through the undersigned counsel, seeks declarations that United States Patent No. 5,245,282 (the "282 Patent") asserted by plaintiff and counterclaim-defendant University of Virginia Patent Foundation ("UVAPF") is not and has not been infringed by GE and is invalid as follows:

THE PARTIES

- 1. GE is a New York corporation with a principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut 06828.
- 2. In paragraph 1 of its Complaint in this action, UVAPF alleges it is a Virginia corporation having a principal place of business at 250 West Main Street, Suite 300, Charlottesville, Virginia 22902.

JURISDICTION AND VENUE

- 3. GE's counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., and under the patent laws of the United States, 35 U.S.C. § 1, et seq.
- 4. This Court has jurisdiction over the counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a) and 2202.
- 5. This Court has personal jurisdiction over counterclaim-defendant UVAPF by virtue of, *inter alia*, UVAPF's filing of the Complaint in this Court.
- 6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b) because this suit was filed in this district by UVAPF and UVAPF is located in this district.
- 7. By virtue of the allegations of plaintiff and counterclaim-defendant UVAPF's Complaint in this action and GE's Answer thereto, an immediate, real, and justiciable controversy exists between GE and UVAPF as to whether the '282 Patent is invalid and not infringed.

FIRST COUNT (Declaration of Noninfringement of the '282 Patent)

- 8. GE restates and incorporates by reference each of the allegations of paragraphs 1 through 7 of these Counterclaims.
- 9. UVAPF claims to be the owner and assignee of all rights, title and interest in and under United States Patent No. 5,245,282.
 - 10. UVAPF alleges infringement of the '282 Patent by GE.
- 11. GE and the customers using its products or services are not infringing and have not infringed any valid claim of the '282 Patent, and UVAPF is entitled to no relief for any claim alleged in the Complaint for, *inter alia*, the reasons stated in the Affirmative Defenses set forth in GE's Answer.

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SECOND COUNT (Declaration of Invalidity of the '282 Patent)

- GE restates and incorporates by reference each of the allegations of paragraphs 1 12. through 7 of these Counterclaims.
 - UVAPF, by its Complaint, contends that the '282 Patent is valid. 13.
- Each and every claim of the '282 Patent in invalid for failing to satisfy one or 14. more of the conditions for patentability specified in Title 35 of the United States Code, including without limitation, Sections 101, 102, 103 and 112.

JURY DEMAND

GE hereby demands a jury trial on all issues and claims so triable.

PRAYER FOR RELIEF

WHEREFORE, GE prays for judgment with respect to GE's Counterclaims as follows:

- that the Court find and declare that the '282 Patent is not infringed by GE or any a. customers using GE's products or services;
 - b. that the Court find and declare that the '282 Patent is invalid;
- that judgment be entered in favor of GE and against UVAPF on each of GE's c. Counterclaims;
- d. that the Court find this an exceptional case and award GE its costs and attorneys' fees pursuant to 35 U.S.C. § 285 or otherwise; and
- that the Court grant GE such other and further relief as the Court deems just and e. proper.

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Attorneys for Defendant GENERAL ELECTRIC COMPANY d/b/a GENERAL **ELECTRIC HEALTHCARE**

CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of September, 2008 I served the attached pleading on C. Connor Crook using the ECF electronic filing system, and on Joseph F. DePumpo, Alfonso G. Chan and Justin B. Kimble by first class mail at Shore, Chan and Bragalone, 325 N. St. Paul St, Suite 4450, Dallas, Texas 75201.

51444/2641391.1